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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,446

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Scott A. Burton

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

08/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/728,446	Applicant(s) BURTON ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-35,37-39 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-35,37-39 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/05/2009; 03/02/2009; 03/25/2009; 04/08/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and IDS, both filed 04/08/2009; IDS filed 03/25/2009; IDS filed 03/02/2009; and IDS filed 02/05/2009.

Claims 1-4, 6-35, 37-39 and 45-50 are pending and included in the prosecution.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 6-35, 37-39 and 45-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-51

of copending Application No. 10/917,002, and over claims 21-30 of copending Application No. 10/917,102. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: method of coating silver compound on a substrate comprising combining silver-containing compound with ammonium-containing compound in a solution, coating the solution on a substrate and drying the substrate. The present claims anticipate the claims of the copending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

3. The examiner acknowledged applicants' intention to provide an appropriate response to overcome provisional obviousness-type double patenting rejection upon an indication of otherwise allowable subject matter.

However, "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-4, 7-14, 25, 37, 45, 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 769,799 ('799) in view of WO 02/43743 ('743).

GB '799 teaches method for coating substrate of fabric, sheet or fibers with sparingly water soluble silver salt including dipping or wetting the substrate surface with solution comprising aqueous solution of silver salt including silver nitrate, and ammonia compound to solubilize the silver salt, followed by drying the wet substrate (page 1, lines 81-85; page 2, lines 1-5, 18-26, 30-36, 112-120; page 3, lines 112-115; the tale in page 6). The coating solution further comprises stabilizer that reads on antioxidant

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claimed by claims 12 and 13, and the stabilizer is added to the coating solution that is applied to the substrate, therefore, the limitations of claims 12 and 13 are met. Drying by heat will inherently remove volatile components of the coated solution and silver will remain. GB '799 teaches that the solution can be coated on medical articles surgical masks and surgeons hats (page 5, lines 123-125). The pH of the coating solution comprising the same ingredients including ammonia is expected to have the same alkaline pH value. The coated substrate is lethal to bacteria and fungi falling on its surface and remains this way for long time (page 2, lines 3-5). GB '799 teaches that dipping the substrate in the solution is carried out at temperature 60 °C 80 °C, however, temperature variation does not produce any significant change in the treated article, and even higher temperature caused color changes (page 6, lines 10-20). The reference further teaches that the sheet is stable and resists prolonged exposure to strong sunlight, which meets the limitation of stable to at least one of visible light, UV light, electron beam, and gamma sterilization (page 5, lines 103-105, 127-128). The reference disclosed applying to an article solution containing the anions of the sparingly water soluble silver salt and also containing a basic nitrogen compound, i.e. ammonia or an amine, which serves as a solubilizer for the sparingly soluble silver salt (page 2, lines 17-27), i.e. both of silver salt and ammonium compound are in single solution prior to application to the article. In page 2, lines 17-27, the reference teaches that: "In many instances the mixture of silver salt, the light stabilizer for the silver salt, and the fungicidal salt are co-precipitated on the surfaces of the article by wetting the surfaces of the article with succession of properly chosen solutions containing the component

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ions of the substances, the solution containing the anions of the sparingly water soluble silver salt also containing a basic nitrogen compound, i.e. ammonia or an amine, which serves as a solubilizer for the sparingly soluble silver salt.” The reference does not teach coating comprising silver metal, i.e. the coating is essentially free of silver metal.

Although GB ‘799 teaches sparingly soluble silver compounds, however, the reference does not explicitly teach the silver compounds as claimed by claims 1, 48-50.

Although GB ‘799 teaches insignificant effect of temperature variation of the dipping solution on the treated article and the disadvantage of higher temperature, however GB ‘799 does not teach specifically temperature less than 40 °C as claimed by claims 3 and 4.

Further GB ‘799 teaches ammonia added to the sparingly water soluble salt solution for solubilizing the solution, however, it does not explicitly teach ammonium salts claimed by claims 7 and 8.

Although GB ‘799 teaches coating medical articles with the disclosed solution, however, the reference does not explicitly teach coating wound dressing.

WO ‘743 teaches wound dressing made of polymer such as hydrocolloid or polymer fibers prepared by method comprising the steps of subjecting the polymer to aqueous solution comprising silver salts such as nitrate and carbonate, and ammonium salt such as acetate or carbonate at ambient temperature, i.e. below 40 °C, and drying the material (page 3, lines 24-30; page 4, lines 1-15; page 5, lines 3, 10-15; page 7, lines 1-3, 12-15, claim 9). The produced material is stable (page 8, line 3). The

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ammonium salts facilitate silver photostabilization (page 7, lines 4-7). The solution further comprises peroxide as stabilizing agent (page 7, lines 4-7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with using an aqueous solution comprising sparingly water soluble silver nitrate and ammonia as disclosed by GB '799, and replace the silver nitrate with silver carbonate as disclosed by WO '743. One would have been motivated to do so because WO '743 disclosed silver nitrate and carbonate as equivalent silver salts that are appropriate silver source for combination with ammonium compound for coating wound dressing. One would have been reasonably expected coating a substrate using silver carbonate and ammonium compound and formulated stable medical devices.

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with silver compound using an aqueous solution comprising sparingly water soluble silver salt and ammonia coated on the article and then drying the article as disclosed by GB '799, and further perform the step of drying the article at ambient temperature as disclosed by WO '734. One would have been motivated to do so because WO '743 teaches range of temperature up to 100 °C, and preferred ambient temperature, and also because GB '799 taught that temperature variations does not have significant effect on the treated article and taught that high temperature is disadvantageous. One would reasonably expect successfully coat a medical article with silver compound using an aqueous solution comprising sparingly

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water soluble silver salt and ammonia on the article followed by drying the article at ambient temperature with less coast and avoidance of deleterious heat effects.

Additionally, it would have been also obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising sparingly water soluble silver salt and ammonia as disclosed by GB '799, and replace the ammonia compound with ammonium carbonate as disclosed by WO '743. One would have been motivated to do so because WO '743 teaches that ammonium carbonate facilitates photostabilization of silver. One would reasonably expect coating a medical article using an aqueous solution comprising sparingly water soluble silver salt and ammonium carbonate wherein the coating is photostable.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising sparingly water soluble silver salt and ammonia as disclosed by GB '799, and use such a coating to coat wound dressing as taught by WO '743. One would have been motivated to do so because GB '799 teaches that article coated with silver salt is lethal to bacteria and fungi falling on its surface and remains this way for long time, and also motivated by the teaching of WO '743 that wound dressing subjected to solution comprising silver salt and ammonium salts is photostable. One would reasonably expect coating a wound dressing with silver compound using an aqueous solution comprising sparingly water soluble silver salt and ammonium compound wherein the dressing is lethal to the microorganisms that come in contact with the surface of the dressing and also photostable.

Response to Arguments

7. Applicant's arguments filed 04/08/2009 have been fully considered but they are not persuasive.

The main gist of Applicants' argument against obviousness rejections of the claims over GB '799 is that the reference teaches using two separate solutions one containing silver salt and the other containing ammonium salt, and does not teach single solution containing silver and ammonium. The reference does not teach mixing both solutions prior to application to the substrate, but multiple solutions.

In response to this argument, applicants' attention is directed to page 2 of the GB '799, lines 17-27, wherein the reference disclosed that: "In many instances the mixture of silver salt, the light stabilizer for the silver salt, and the fungicidal salt are co-precipitated on the surfaces of the article by wetting the surfaces of the article with succession of properly chosen solutions containing the component ions of the substances, the solution containing the anions of the sparingly water soluble silver salt also containing a basic nitrogen compound, i.e. ammonia or an amine, which serves as a solubilizer for the sparingly soluble silver salt." Therefore, GB '799 clearly disclosed combination of both silver salts and ammonium containing compounds in one solution prior to application to the article, and also disclosed that ammonium containing compound will solubilize the silver salt, and that will form clear solution since the sparingly soluble silver salt is solubilized. The reference further teaches mixing the two solutions prior to dipping of the substrate, and dipping form coating on the substrate.

Elimination of the step of forming two separate solutions: one containing silver compound and the other containing ammonium, and forming one solution containing both elements is obvious since both of solutions are eventually mixed in the following step when applied to the substrate. It has been held that it is obvious to eliminate of a step and its function if the step is not desired. *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). It has been held that reversing of order of the prior art process is *prima facie* obvious absence superior and unexpected results, see *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). Selection of any order of performing process steps is *prima facie* obvious in absence of new unexpected results, see *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). Any order of mixing ingredients is *prima facie* obvious, see *In re Gibson* 39 F.2d 975, 5USPQ 330 (CCPA 1930). Therefore, mixing the silver containing solution with the ammonium containing solution prior or after application on the substrate is not a detrimental step since mixing of both is taught by the prior art.

Although applicants admit that WO '743 teaches ammonium salts (such as ammonium carbonate) to facilitate silver photostabilization, however argue that the ammonia or amine, which serves as a solubilizer in GB '799 is removed by vaporization, thus, it is not present on the dried article. So, it is not clear that the ammonia or amine could be assisting in photostabilization of the silver on the dried article. Therefore, there is no motivation to combine the teachings of WO '743 with GB '799.

In response to this argument, it is argued that WO '743 is relied upon for teaching the specific silver compounds including silver bicarbonate and the specific ammonium compounds, and for teaching wound dressings coated with silver containing compounds. WO '743 further teaches the equivalency between the silver compounds taught by GB '799 and silver carbonate in terms of suitability as a coating for a wound dressing. GB '799 does not teach removal of the solubilizer, rather teaches removal of volatile components of the solution.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article with using an aqueous solution comprising sparingly water soluble silver nitrate and ammonia as disclosed by GB '799, and replace the silver nitrate with silver carbonate as disclosed by WO '743. One would have been motivated to do so because WO '743 disclosed silver nitrate and carbonate as equivalent silver salts that are appropriate silver source for combination with ammonium compound for coating wound dressing. One would have been reasonably expected coating a substrate using silver carbonate and ammonium compound and formulated stable medical devices.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

8. Claims 6, 15-24, 26-35, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '799 combined with WO '743 and further in view of US 4,592,920 ('920).

The combined teachings of GB '799 and WO '743 are previously discussed as set forth in this office action.

Although GB '799 teaches sparingly water soluble silver salts and ammonium compounds for coating a substrate, however, the reference does not explicitly teach silver oxide as claimed by claims 6, 15, 27, and claims depends therefrom.

US '920 teaches coating of medical devices with coating containing antimicrobial metal that is biocompatible with body including silver oxide (abstract; col.2, lines 1-3; col.3, lines 22-25, 32-33).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising

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sparingly water soluble silver salt and ammonia as disclosed by GB '799 combined with WO '743, and replace the silver salt with silver oxide disclosed by US '920. One would have been motivated to do so because US '920 teaches that silver oxide is biocompatible with body. One would reasonably expect coating a medical article with an aqueous solution comprising silver oxide and ammonia compound wherein the coating is safe and biocompatible with the body.

9. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of GB '799 and WO '743, and further in view US 2003/0054025 ('025).

The combined teachings of GB '799 and WO '743 are previously discussed as set forth in this office action.

Although GB '799 teaches coating of the composition containing silver salt and ammonium compound on a substrate, however, the reference does not explicitly teach spray coating as instantly claimed by claim 46.

US '025 teaches non-contact printing methods for coating medical article (abstract; paragraph 0002). The coating is a liquid medicinal agent coated on a base layer (paragraph 0029). Preferred non contact printing includes spray printing (paragraphs 0030, 0035). The medicinal agent includes silver containing compounds (paragraph 0048). The reference disclosed that after printing, the liquid composition is sufficiently dried to allow for lamination, wind-up, or storage (paragraph 0039).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising

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sparingly water soluble silver salt and ammonia on the article as disclosed by GB '799 combined with WO '743, and use spraying method taught by US '025 for coating the substrate. One would have been motivated to do so because US '025 teaches that spray coating of medicinal liquid containing silver compounds on a substrate is a preferred coating method. One would reasonably expect coating a substrate of medical device by spraying a liquid comprising silver salt and ammonium compound.

10. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of GB '799, WO '743 and US '920, and further in view US '025.

The combined teachings of GB '799, WO '743 and US '920 are previously discussed as set forth in this office action.

Although GB '799 teaches coating of the composition containing silver salt and ammonium compound on a substrate, however, the reference does not explicitly teach spray coating as instantly claimed by claim 47, which is taught by US '025. The teaching of US '025 is previously discussed.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to coat a medical article using an aqueous solution comprising sparingly water soluble silver oxide and ammonia on the article as disclosed by GB '799 combined with WO '743 and US '920, and use spraying method taught by US '025 for coating the substrate. One would have been motivated to do so because US '025 teaches that spray coating of medicinal liquid containing silver compounds on a substrate is a preferred coating method. One would reasonably expect coating a

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substrate of medical device by spraying a liquid comprising silver oxide and ammonium compound.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG